DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[30Day-22-22BJ]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Agency for Toxic Substances and Disease Registry (ATSDR) has submitted the information collection request titled Evaluating the Association between Serum Concentrations of Per- and Polyfluoroalkyl substances (PFAS) and Symptoms and Diagnoses of Selected Acute Viral Illnesses to the Office of Management and Budget (OMB) for review and approval. ATSDR previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on April 5, 2021 to obtain comments from the public and affected agencies. ATSDR did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

ATSDR will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Evaluating the Association between Serum Concentrations of Per- and Polyfluoroalkyl Substances (PFAS) and Symptoms and Diagnoses

of Selected Acute Viral Illnesses – New - Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

Per- and poly-fluoroalkyl substances (PFAS) are a large, diverse group of thousands of chemicals that have been used extensively in a wide range of industrial and consumer applications. Epidemiological studies have evaluated the associations between PFAS exposure and health effects in humans. Evidence from these studies in occupationally exposed populations, residential populations exposed to higher levels of PFAS in drinking water, and studies in the general population suggest associations between PFAS and several health outcomes.

Exposure to PFAS is nearly ubiquitous in the United States. Epidemiological studies suggest that PFAS exposure may impact the immune system and susceptibility to viral infections. However, there is little consistency in the results of studies on PFAS exposure and infectious disease. The coronavirus disease 2019 (COVID-19) pandemic presents a unique concern and opportunity to explore this association. If PFAS affect the immune system, it is possible that they could affect susceptibility to infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, or could affect severity of COVID-19 symptoms.

In 2019 and 2020, the Agency for Toxic Substances and Disease Registry (ATSDR) conducted statistically based biomonitoring PFAS exposure assessments (EAs) in eight

communities that had documented exposures to PFAS in drinking water. ATSDR also supported two EAs that were designed to test the PFAS Exposure Assessment Technical Tools (PEATT). PFAS concentrations were measured in serum collected from EA and PEATT assessment participants, and a questionnaire was administered to gather information to characterize each individual's exposure. These communities were investigated under "Per- or Polyfluoroalkyl Substances Exposure Assessments [PFAS EAs]" (OMB Control No. 0923-0059, expiration date 06/30/2022). During the same period, ATSDR initiated a health study at the Pease International Tradeport that included measurement of PFAS serum levels and collection of information about individual exposures in participants under "Human Health Effects of Drinking Water Exposures to Per- and Polyfluoroalkyl Substances (PFAS) at Pease International Tradeport, Portsmouth, NH (The Pease Study)" (OMB Control No. 0923-0061, expiration date 08/31/2022).

This a new two-year ATSDR information collection request (ICR) for a collaborative study between the Centers for Disease Control and Prevention's National Center for Environmental Health (CDC/NCEH) and ATSDR. This follow-up study will recruit participants who; 1) participated in a previous ATSDR-funded study, 2) have existing serum-PFAS measurements, and 3) have given prior consent for additional contact from NCEH/ATSDR. We anticipate that the total number of participants enrolled in the CDC/ATSDR cohorts will be around 3,170 (2,800 adults and 370

children) individuals. This study will attempt to enroll the entire universe of eligible participants; therefore, our target sample size is 3,170. The cohorts have a substantial number of participants with high PFAS exposure, as well as a sufficient range of serum-PFAS concentrations to allow examination of associations between the outcomes and across a wide range of PFAS exposures.

The objectives are the following: (1) to examine the association between serum-PFAS collected through the EAs, PEATT assessments, and Pease Study and the frequency of occurrence of selected syndromes (combinations of self-reported symptoms), which will be used as a proxy for viral infections; and, (2) to examine the association between serum-PFAS collected through the EAs, PEATT assessments, and Pease Study and self-reported positive test results indicating specific viral infections.

During the first three months of the two-year study period, NCEH/ATSDR will invite and consent approximately 3,170 participants (2,800 adults and 370 children) to complete a new series of surveys to determine whether PFAS exposure increases susceptibility to viral infections, including, but not limited to COVID-19. Data will be collected from those who enroll in the study through an initial paper-based survey and a series of four additional surveys over a 12- to 14-month period. Follow-up surveys will be offered in two modes: web-based and paper-based. It is estimated that 75% of the participants will choose the web-based mode. Participants will also be given symptom diaries

to improve recall after the initial and between each of the follow-up surveys.

The total time burden requested is 19,816 hours (or 9,908 hours annually). There are no costs to the respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hr)
Adults	Initial Questionnaire - Adult (paper)	700	1	30/60
	Follow up Questionnaire - Adult (paper)	175	4	30/60
	Follow up Questionnaire - Adult (REDCap)	525	4	25/60
	Symptom Diary	700	1	4
Children (7-17 years)	Initial Questionnaire - Child (paper)	70	1	30/60
	Follow up Questionnaire - Child (paper)	18	4	30/60
	Follow up Questionnaire - Child (REDCap)	52	4	25/60
	Symptom Diary	70	1	4
Parents of Children (3-6 years)	Initial Questionnaire - Child (paper)	12	1	30/60
	Follow up Questionnaire	6	4	30/60

	- Child (paper)			
	Follow up Questionnaire - Child (REDCap)	18	4	25/60
	Symptom Diary	23	1	4

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